

Complete Summary

GUIDELINE TITLE

Rimonabant for the treatment of overweight and obese adults.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Rimonabant for the treatment of overweight and obese adults. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jun. 30 p. (Technology appraisal guidance; no. 144).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Overweight
- Obesity

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of rimonabant for the treatment of overweight and obese adults

TARGET POPULATION

Overweight and obese adults

INTERVENTIONS AND PRACTICES CONSIDERED

Rimonabant as an adjunct to diet and exercise

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
 - Body weight and body mass index (BMI) change from baseline at 1 and 2 years
 - Proportion of patients achieving 5% or 10% weight loss
 - Change in waist circumference
 - Quality of life
 - Safety and tolerability (adverse events and withdrawal due to adverse events)
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology

considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Centre for Health Economics, University of York and Centre for Reviews and Dissemination, University of York (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Description of Manufacturers Search Strategy and Comment on whether the Search Strategy Was Appropriate

The submission reports a search of most of the required databases for records of reviews and randomized controlled trials relating to effects of rimonabant, sibutramine and orlistat. NICE requires a search of the Cochrane Library, but the submission reports only a search of the Cochrane Database of Systematic Reviews. This may mean that the CENTRAL Register of Clinical Trials, Database of Abstracts of Reviews of Effectiveness (DARE) and the Health Technology Assessment (HTA) database were not searched. The submission reports that an additional relevant database, Biosis, was searched.

A MEDLINE search strategy only is reported. The database searches were reported to have been run on Datastarweb, but the search syntax (truncation symbols, etc.) reported is not correct for Datastarweb. The ERG was unable to rerun the strategy, as presented, in the PubMed, Datastarweb or Ovid interfaces to MEDLINE. The ERG was also unable to verify how the strategy was adapted for databases other than MEDLINE. However, the structure of the search strategy as reported is suitable for capturing the topic in MEDLINE.

The words used in the strategies for identifying evidence on the effects of rimonabant, sibutramine and orlistat are adequate to capture the topic. One search term reported is not a MeSH term (HYPERLIPIDAEMIA). The relevant MeSH terms for the topics in this section of the strategy should be DISLIPIDEMIAS/, HYPERLIPIDEMIAS/ and HYPERCHOLESTEROLEMIA/.

The submission records that reference lists of retrieved papers were reviewed to identify additional articles. This is accepted practice.

The manufacturer identified data from unpublished trials presented at conferences from its own files only: "unpublished data held on file by Sanofi-Aventis". Data from SERENADE and REBA trials are included in the submission. Searches of other external resources for trial information in the form of presentations, abstracts and posters were not reported to have been undertaken. In response to a request for clarification, the manufacturer stated that they did not search for data from ongoing (soon to report) studies.

Statement of the Inclusion/Exclusion Criteria Used in the Study Selection and Comment on whether They Were Appropriate

The manufacturer identified three base-case populations:

- Overweight or obese patients with treated type 2 diabetes

- Overweight or obese patients with dyslipidaemia (defined as triglycerides >1.7 mmol/L or total plasma cholesterol >5.0 mmol/L or low-density lipoprotein cholesterol [LDL-C] >3.0 mmol/L or high-density lipoprotein cholesterol [HDL-C] <1.03 mmol/L for men, and triglycerides >1.7 mmol/L or total plasma cholesterol >5.0 mmol/L or LDL-C >3.0 mmol/L or HDL-C <1.29 mmol/L for females) not treated with a statin, and without type 2 diabetes
- Overweight and/or obese patients with or without comorbidities, without diabetes.

These groups seem to reflect the Rimonabant in Obesity (RIO) trials rather than subgroups of importance in clinical practice. A notable omission is a subgroup of patients with hypertension.

For the review of orlistat and sibutramine the inclusion criteria were:

- Studies of 1 year duration (or data available for 1 year).
- Diet and exercise administered to placebo and treatment arms.
- Data for intention to treat (ITT) population available (if this was not stated, it was assumed that data presented in the studies were for the ITT population and they were not excluded).
- Orlistat dose of 120 mg three times a day (tid) or 120 mg with each meal.
- Sibutramine dose of 10 or 15 mg/day.
- Data relating to trial run-in periods (if applicable) were excluded from the analysis.

The inclusion criteria for the doses of orlistat and sibutramine appear clinically appropriate. All the trials evaluating orlistat included the dose of 120 mg three times daily as specified in the inclusion criteria; several trials also evaluated 30 mg or 60 mg three times daily. Two of the included sibutramine trials did not appear to meet the inclusion criteria; these two trials evaluated 20 mg of sibutramine once daily. Data for orlistat and sibutramine were only sought for 1 year; although this is appropriate for sibutramine given its licence, orlistat can be prescribed for longer, and two year data may have been available for comparison with the longer-term outcomes reported in the RIO trials.

The submission states that studies were screened by a single reviewer at both the title/abstract stage and the full paper stage, with a second reviewer screening only approximately 10% of identified studies. This could lead to missed studies and selection bias, particularly when considering the orlistat and sibutramine trials as it seems that some of the reasons for exclusion could be deemed subjective and judgements may vary between reviewers. In addition, no description is provided of methods for resolving disagreements where dual screening was undertaken.

Cost-Effectiveness

Existing Cost-Effectiveness Evidence

As part of the manufacturer's submission, a systematic search was undertaken with the aim of identifying all studies evaluating the cost-effectiveness of rimonabant, orlistat and sibutramine for the treatment of obesity. No studies of the cost-effectiveness of rimonabant were identified by the manufacturer as part

of this search. However, one study which appears to have been published after the search was undertaken, was reported by the manufacturer. The search strategy was critically appraised by an experienced information scientist within the ERG.

Although the manufacturer undertook a search of most of the required databases for studies of the cost-effectiveness, a search of the Cochrane Library was not conducted. However, searches of additional relevant databases were undertaken: including National Health Service Economic Evaluation Database (NHS EED), Health Economic Evaluations Database (HEED) and Biosis.

A MEDLINE search strategy only is reported. The database searches were reported to have been run on Datastarweb. However, the search syntax reported is not correct for Datastarweb. The ERG was therefore unable to rerun the strategy as presented in the PubMed, Datastarweb or Ovid interfaces to MEDLINE. In addition, the ERG was unable to verify how the strategy was adapted for databases other than MEDLINE. However, the structure of the search strategy as reported was considered suitable for capturing rimonabant cost-effectiveness studies in MEDLINE. In addition, the words used in the strategy are adequate to capture the topic. Sensitivity might have been enhanced by the use of additional quality of life terms, such as "quality-adjusted", "qalys", etc.

Although unable to re-run the searches as reported in the submission, the ERG translated the strategy generously (assuming broad searches of all fields for terms that were not subject headings) and ran it in MEDLINE (1950 to 28 September 2007) on Datastarweb. The translated search yielded 10 records. The strategies used with the other databases were not reported so it was not possible to replicate or translate them. No additional studies relating to the cost-effectiveness were identified using the translated search.

The study mentioned in the manufacturer's submission evaluated the cost-effectiveness of rimonabant compared to diet and exercise from a UK NHS perspective. This study is based on the same model used as part of the manufacturer's own submission and hence is not considered in any more detail by the ERG.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

Six published reports and 2 unpublished trials were included.

Cost-Effectiveness

A manufacturer's model was submitted.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Centre for Health Economics, University of York and Centre for Reviews and Dissemination, University of York (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Description and Critique of Manufacturer's Approach to Validity Assessment

The manufacturer used appropriate criteria to assess the quality of the Rimonabant in Obesity (RIO) trials. Brief study details and methods for randomisation and allocation concealment were provided on request by the ERG; these seemed adequate for all three trials. Neither the dropout rates, nor the basis for the sample size calculations were provided by the manufacturer for these trials. There are a number of discrepancies between the validity assessment provided in the submission and the information available in published trial reports. These discrepancies are primarily information that is lacking in the published papers, relating principally to adequacy of allocation concealment and power calculations, which is reported in the manufacturer's submission. It is assumed that these discrepancies stem from access to full trial reports that included unpublished detail of trial methodology.

Describe and Critique the Statistical Approach Used

Handling of Missing Data

The manufacturers used a last observation carried forward (LOCF) to deal with the dropouts. However, to investigate the impact of such high drop out rates further (ranging from 23% to 60% across the RIO trials), a best case/worst case scenario may have been appropriate given that many patients may have dropped out due to lack of success and loss of motivation. The manufacturer was requested by the ERG to justify the sole use of LOCF in their submission. The manufacturer provided further details relating to the use of LOCF, and tables of the results from each of the RIO trials as analysed using LOCF, baseline observation carried forward, and repeated measures. The ERG were satisfied that the LOCF provided conservative results for each outcome.

From the methods reported by the manufacturer, it is not clear whether data extraction was conducted in duplicate, or whether extracted data was checked by an independent reviewer; the discrepancies highlighted reduce the confidence in both the acquisition, and use, of the data from orlistat and sibutramine.

Meta-Analysis of Weight Loss and Cardiovascular and Diabetes Risk-Related Outcome Data

Standard meta-analyses techniques were used to pool weight loss-related data. A fixed effect model was used when the p-value of the Chi-squared test for heterogeneity was ≥ 0.1 , and a random effects model when the p-value was < 0.1 . An *a priori* decision was made that patients with diabetes were too clinically different from other overweight or obese patients to be included in the main meta-analyses of weight loss-related data. Thus data from RIO-North America, RIO-Europe and RIO-Lipids were pooled, and data from RIO-diabetes presented separately. Clinical advice to the ERG confirms that presenting the results separately for a diabetic sub-group was appropriate, but presenting results for the whole population would also be appropriate.

In addition to the meta-analyses based on published data, the manufacturer also provided pooled patient-level data. They provided these for non-diabetic patients (RIO-North America, RIO-Europe and RIO-Lipids) and for treated dyslipidaemics (RIO-North America, RIO-Europe).

Refer to Section 4.1 of the ERG report (see the "Availability of Companion Documents" field) for more information on methods used to analyze the clinical evidence.

Cost-Effectiveness

Overview of Manufacturer's Economic Evaluation

The manufacturer's submission evaluates the cost-effectiveness of rimonabant (20 mg once daily), as an adjunct to diet and exercise, for the treatment of obesity (body mass index [BMI] ≥ 30 kg/m²), and overweight patients (BMI ≥ 27 kg/m²) with associated risk factors. Rimonabant is compared with orlistat (120 mg three times a day or with each meal), sibutramine (10 to 15 mg per day) and non-pharmacological (diet and exercise alone) therapies.

Refer to Table 5.1 in the ERG report (see the "Availability of Companion Documents" field) for the summary of manufacturer's economic evaluation and to Section 5 of the ERG report for a complete discussion and critique of the manufacturer's model.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The manufacturer's submission included an economic evaluation of rimonabant based on a Markov model.

Across the base-case populations, the incremental cost-effectiveness ratio (ICER) of rimonabant ranged from approximately 10,500 pounds sterling to 13,200 pounds sterling per additional quality-adjusted life year (QALY) gained versus diet and exercise alone, approximately 9000 pounds sterling to 12,100 pounds sterling per QALY gained versus orlistat and approximately 1500 pounds sterling to 3900 pounds sterling per QALY gained versus sibutramine. In the additional subgroups, none of the individual pairwise ICERs for rimonabant exceeded 20,000 pounds sterling per QALY gained. The ICERs across the majority of the sensitivity analyses were broadly consistent with the base-case results.

The Evidence Review Group (ERG) considered the economic model structure to be appropriate for the decision problem. In addition, the ERG considered the general approach employed by the manufacturer (in the absence of long-term event data) of translating changes in intermediate risk factors to changes in event rates was appropriate for the purpose of estimating lifetime cost effectiveness. However, the ERG identified a number of potential issues related to the manufacturer's economic submission that it considered compromised the validity of the model results.

The Institute asked for clarification on the cost effectiveness of rimonabant after accounting for the concerns expressed by the ERG relating to: a lack of simultaneous comparison involving the full range of relevant alternatives; the absence of treatment continuation rules for orlistat and sibutramine in line with their UK marketing authorisations and uncertainty surrounding the health-related quality of life (HRQoL) data reported in the clinical trials, and the estimates employed in the model. The ERG also conducted exploratory analyses to reflect treatment continuation rules and different assumptions on the effect of body mass index (BMI) on HRQoL. The ICER of rimonabant remained relatively robust throughout the re-analyses by the manufacturer and the exploratory analysis by the ERG (less than 30,000 pounds sterling per additional QALY gained), although the ERG noted several important caveats that needed to be considered. These included the most appropriate way to incorporate response hurdles; the uncertainty surrounding the direct impact of weight loss on cardiovascular and diabetes-related events; HRQoL benefits of rimonabant and the maintenance of benefits over the longer term.

Following a request from the Committee, the manufacturer submitted additional data from the four clinical trials on the health outcomes of adults who responded to treatment with rimonabant (defined as at least 5% weight loss at 3, 6, 9 and 12 months). The manufacturer presented analyses for two populations: overweight or obese people (BMI greater than 27 kg/m²) with diabetes, and obese people (BMI 30 kg/m² or greater) with or without risk factors including diabetes.

Following a request from the Committee, the manufacturer also revised its estimates of the cost effectiveness of rimonabant compared with diet and exercise alone, with orlistat and with sibutramine. For all treatments the manufacturer included alternative linear deteriorations in treatment effect and the discontinuation of treatment if the person returns to their original weight.

The manufacturer presented cost-effectiveness results for overweight or obese people with diabetes and obese people with and without risk factors (including diabetes). With a 6-month continuation rule, the ICER for rimonabant compared with diet and exercise was approximately 19,000 pounds sterling per QALY gained in the overweight or obese people with diabetes and approximately 11,900 pounds sterling per QALY gained in people who were obese with and without risk factors. The ICERs for rimonabant compared with orlistat were approximately 28,700 pounds sterling and 23,600 pounds sterling per QALY gained, respectively. The manufacturer was unable to compare rimonabant with sibutramine in people who were obese with and without risk factors because there was a lack of comparable data. The ICER for rimonabant compared with sibutramine in overweight or obese people with diabetes was approximately 30,700 pounds sterling.

The Committee noted that the manufacturer's revised estimates of cost effectiveness for rimonabant compared with sibutramine and orlistat were greater than 20,000 pounds sterling per QALY gained. It concluded that some of the assumptions in the model may have led to underestimation of the ICERs, particularly relating to the long-term effect on cardiovascular disease and diabetes and the costs and quality of life associated with treatment-related depression. Therefore the Committee could not recommend rimonabant as an alternative to orlistat and sibutramine.

The Committee discussed the use of rimonabant as a treatment option for adults who have had an inadequate response to, are unable to tolerate, or have a contraindication to appropriate use of orlistat and sibutramine. The Committee concluded that the appropriate comparator was diet plus exercise alone. The Committee noted that the ICER for rimonabant versus diet and exercise was below 20,000 pounds sterling. The Committee was mindful of the possibility that the ICER may be higher, given the concerns described above, but concluded that the ICER was unlikely to increase beyond that considered to be a reasonable use of National Health Service (NHS) resources. The Committee also considered the lack of alternative options in this group of people for whom other treatments have failed. It concluded that rimonabant is a cost-effective option for adults who have had an inadequate response to, are unable to tolerate or have a contraindication to orlistat and sibutramine.

Refer to Sections 3 and 4 of the original guideline document for details of the economic analyses provided by the manufacturer, the ERG comments, and the Appraisal Committee considerations.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This guidance should be read in conjunction with 'Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children' (National Institute for Health and Clinical Excellence [NICE] clinical guideline 43). In addition, when considering the presence of current or previous depressive disorders/mood alterations, and during regular monitoring for the emergence of such symptoms, use should be made of the NICE clinical guidelines on the management of anxiety and depression (NICE clinical guidelines 22 and 23), noting the need for careful and comprehensive assessment.

- Rimonabant, within its licensed indications, is recommended as an adjunct to diet and exercise for adults who are obese or overweight and who have had an inadequate response to, are intolerant* of or are contraindicated to orlistat and sibutramine.
- Rimonabant treatment should be continued beyond 6 months only if the person has lost at least 5% of their initial body weight since starting rimonabant treatment.
- Rimonabant treatment should be discontinued if a person returns to their original weight while on rimonabant treatment.
- Rimonabant treatment should not be continued for longer than 2 years without a formal clinical assessment and discussion of the individual risks and benefits with the person receiving treatment.

*Steatorrhoea as a consequence of not adhering to dietary advice should not be considered as intolerance to orlistat.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by randomized controlled trials and a *de novo* economic evaluation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of rimonabant for the treatment of overweight and obese adults

POTENTIAL HARMS

Adverse events associated with rimonabant include nausea, vomiting, diarrhoea, dry mouth, anorexia, depression, anxiety, irritability, nervousness, sleep disorders, and impaired memory and attention.

For full details of adverse events and contraindications, see the summary of product characteristics (SPC).

CONTRAINDICATIONS

CONTRAINDICATIONS

Rimonabant is contraindicated in people with major depressive illness or those receiving concomitant treatment with antidepressants, people with uncontrolled psychiatric illness and people with severe renal impairment. The summary of product characteristics (SPC) states that if depression or psychiatric illness is diagnosed during rimonabant therapy, treatment must be stopped.

For full details of adverse events and contraindications, see the SPC.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organizations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (www.nice.org.uk//TA144 [see also the "Availability of Companion Documents" field]).
 - Costing report and costing template to estimate the savings and costs associated with implementation
 - Audit support for monitoring local practice

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

Patient Resources

Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Rimonabant for the treatment of overweight and obese adults. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jun. 30 p. (Technology appraisal guidance; no. 144).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Jun

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr Jeff Aronson, Reader in Clinical Pharmacology, Radcliffe Infirmary, University of Oxford; Dr Darren Ashcroft, Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Professor David Barnett, Professor of Clinical Pharmacology, University of Leicester; Professor John Cairns, Public Health and Policy, London School of Hygiene and Tropical Medicine; Dr Mark Charkravarty, Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK); Ms Lynn Field, Nurse Director, Pan Birmingham Cancer Network; Professor Christopher Fowler, Professor of Surgical Education, University of London; Dr Fergus Gleeson, Consultant Radiologist, Churchill Hospital, Oxford; Ms Sally Gooch, Former Director of Nursing & Workforce Development, Mid Essex Hospitals Services NHS Trust; Mr Sanjay Gupta, Former Service Manager in Stroke, Gastroenterology, Diabetes and Endocrinology, Basildon and Thurrock University Hospitals Foundation NHS Trust; Mr Terence Lewis, Mental Health Consultant, National Institute for Mental Health in England; Professor Gary McVeigh, Professor of

Cardiovascular Medicine, Queens University, Belfast; Dr Ruairidh Milne, Senior Lecturer in Health Technology Assessment, National Coordinating Centre for Health Technology; Dr Neil Milner, General Medical Practitioner, Sheffield; Dr Rubin Minhas, General Practitioner, CHD Clinical Lead, Medway PCT; Dr John Pounsford, Consultant Physician, Frenchay Hospital, Bristol; Dr Rosalind Ramsay, Consultant Psychiatrist, Adult Health Services, Maudsley Hospital, London; Dr Lindsay Smith, General Practitioner, East Somerset Research Consortium; Mr Cliff Snelling, Lay member; Professor Ken Stein (*Vice Chair*) Professor of Public Health, Peninsula Technology Assessment Group (PenTAG), University of Exeter; Dr Rod Taylor, Associate Professor in Health Services Research, Peninsula Medical School, Universities of Exeter and Plymouth

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Rimonabant for the treatment of overweight and obese adults. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jun. 2 p. (Technology appraisal 144). Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Rimonabant for the treatment of overweight and obese adults. Costing template. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jun. Various p. (Technology appraisal 144). Available in Portable Document Format (PDF) from the [NICE Web site](#).
- Rimonabant for the treatment of overweight and obese adults. Audit support. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008. 6 p. (Technology appraisal 144). Available in Portable Document Format (PDF) from the [NICE Web site](#).
- Rimonabant for the treatment of overweight and obese patients. Evidence review group's report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Dec. 135 p. (Technology appraisal 144). Available in Portable Document Format (PDF) from the [NICE Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1606. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Rimonabant for overweight and obese adults. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jun. 4 p. (Technology appraisal 144).

Electronic copies: Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1607. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on September 18, 2008.

The National Institute for Health and Clinical Excellence (NICE) has granted the National Guideline Clearinghouse (NGC) permission to include summaries of their Technology Appraisal guidance with the intention of disseminating and facilitating the implementation of that guidance. NICE has not verified this content to confirm that it accurately reflects the original NICE guidance and therefore no guarantees are given by NICE in this regard. All NICE technology appraisal guidance is prepared in relation to the National Health Service in England and Wales. NICE has not been involved in the development or adaptation of NICE guidance for use in any other country. The full versions of all NICE guidance can be found at www.nice.org.uk.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 11/3/2008

